

**K894681 REVISED LABELING FOR ARTERIAL EMBOLECTOMY
CATHETER**Oct 12, 1989
79 days to decisionK894681 · Product code: **DXE** · Cardiovascular
Source: <https://www.510kdatabase.net/k894681/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Embolectomy (DXE)
Date received	Jul 25, 1989
Decision date	Oct 12, 1989
Days to decision	79 days
Third-party review	No

APPLICANT

Company	Shiley, Inc.
Location	Mchenry, IL, US
Contact	LOUIS J MAZZARESE
510(k) history	174 submissions · 174 cleared · 1976-1993

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k894681/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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